Press Release

PharmaEngine announces its partner, Nanobiotix, received an IND approval from US FDA to conduct a Phase I/II trial of PEP503（NBTXR3）with anti-PD-1 antibodies in non-small cell lung cancer and head and neck cancer

Taipei, Taiwan, December 27, 2017 – PharmaEngine, Inc. (TWO: 4162), announced that its partner, Nanobiotix (Euronext: NANO), has been granted an Investigational New Drug (IND) approval by the U.S. Food and Drug Administration (FDA) for PEP503 (NBTXR3) activated by radiotherapy, and administered in combination with an anti-PD1 antibody (nivolumab or pembrolizumab).

For further information please refer to the following link：
http://www.nanobiotix.com/download/news_en/2017/Nanobiotix_PR-FDA_approves_NANOBIOTIXs_first_immuno_oncology_trial.pdf

Press Release

FDA APPROVES NANOBIOTIX'S FIRST IMMUNO-ONCOLOGY TRIAL: A PHASE I/II STUDY OF NBTXR3 ACTIVATED BY RADIATION THERAPY (SABR) FOR PATIENTS WITH NON-SMALL CELL LUNG CANCER OR HEAD AND NECK SQUAMOUS CELL CARCINOMA CANCER TREATED WITH AN ANTI-PD1 ANTIBODY (NIVOLUMAB OR PEMBROLIZUMAB)

- **First Nanobiotix immuno-oncology trial will be conducted in the U.S.**
- **Multi-arm trial targets sub-population of advanced and metastatic lung (NSCLC), and head and neck cancer patients (HNSCC).**
- **Evaluation of NBTXR3's potential to turn anti-PD1 inhibitor (nivolumab or pembrolizumad) non-responders at 12 weeks into responders**
- **Trial will also include Head & Neck (HNSCC) cancer patients that are anti-PD1 inhibitor naïve**
- **Expands the potential for NBTXR3 to help locoregionally recurrent or metastatic disease patients through reirradiation or treatment in a single lung or liver metastase**

Paris, France and Cambridge, Massachusetts, USA, December 26, 2017 – NANOBIOTIX (Euronext: NANO – ISIN: FR0011341205), a late clinical-stage nanomedicine company pioneering new approaches to the treatment of cancer, today announced the U.S. Food and Drug Administration (FDA) has approved its Investigational New Drug (IND) Application for NBTXR3, a first-in-class nanoparticle designed for direct injection into cancerous tumors, activated by stereotactic ablative radiotherapy (SABR) and administered in combination with an anti-PD1 antibody (nivolumab or pembrolizumab).

Laurent Levy, CEO of Nanobiotix, stated: "*The FDA's approval of Nanobiotix's IND application for this trial is a major milestone for our Company.We're ready and excited to launch our first immuno-oncology clinical trial in the U.S. combining NBTXR3 with a checkpoint inhibitor. Advancing our demonstration of NBTXR3's potential to turn checkpoint inhibitor non-responders into responders could be game-changing, and the approach could address the unmet medical needs of a significant number of patients. Based on existing pre-clinical and clinical data, NBTXR3 could become a backbone in immuno-oncology*."

The IND approval enables Nanobiotix to initiate NBTXR3-1100, a Phase I/II prospective, multi-center, open-label, and non-randomized clinical trial evaluating the efficacy and safety of NBTXR3 activated by SABR combined with checkpoint inhibitors (nivolumab or pembrolizumab). NBTXR3-1100 includes three cohorts of patients with recurrent and/or metastatic head and neck squamous cell carcinoma (HNSCC), or with metastatic non-small cell lung cancer (NSCLC). The study will be conducted in two consecutive phases. The first of these will be dose escalation, followed by a dose expansion phase. The study will seek to enroll between 36 to 72 patients in Phase I and 40 patients in Phase II.

NBTXR3-1100's dose escalation phase is based on a classical 3+3 Phase I study and planned as a 3-level program to identify the appropriate dose of NBTXR3 injected into the tumor as well as the activation dose of SABR. While NBTXR3 and Radiotherapy doses will be escalated, the anti-PD1 antibody dose will remain constant. One approved anti-PD1 antibody for the dose expansion phase will be selected based on the preliminary risk-benefit ratio assessment observed in Phase I portion of the trial.

Primary and secondary endpoints will evaluate efficacy and safety, while exploratory endpoints further characterize the treatment-induced genomic alterations previously reported, including enriched cytokine activity and markers of adaptive immune response and T-cell receptor signaling pathways.

The NBTXR3-1100 trial will be led by coordinating investigator Tanguy Seiwert, M.D., of The University of Chicago

Medical Center, and principal investigator Jared Weiss, M.D., of The University of North Carolina – Chapel Hill.

The potential for immuno-oncology agents to boost immune system response by priming it for active attack against tumor cells has long been a source of excitement.

While the response to checkpoint inhibitors in so-called "hot" tumors, infiltrated by T-cells and characterized by an inflammatory profile, has been striking with long-lasting clinical benefits in some cancer patients, most patients exhibit little or no response to existing treatments.

According to published data, only 15% to 20% of non-small-cell lung cancer patients (NSCLC), and 13% to 22% of head and neck squamous cell carcinoma patients (NHSCC) respond to current immunotherapy treatments.

The physical mode of action by which NBTXR3 works induces a different immunogenicity and could be the key to significantly increasing the number of cancer patients who can benefit from immuno-oncology therapies.

As presented earlier this year at ASCO & SITC 2017, NBTXR3 activated by radiotherapy was shown to induce a specific adaptive immune pattern that could potentially convert a non-responder into an immune-responsive patient receptive to treatment with available checkpoint inhibitors.

On top of NBTXR3's core developments as a single agent across seven oncology indications, Nanobiotix's immuno-oncology combination program opens the door to new developments, potential new indications, and important value creation opportunities.

The first patient first visit in the potentially paradigm changing trial is expected in Q2 2018 with with first expected results in the summer of 2019.

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About Nanobiotix's immuno-oncology research program

Many IO combination strategies focus on 'priming' the tumor, which is now becoming a prerequisite of turning a "cold" tumor into a "hot" tumor.

Compared to other modalities that could be used for priming the tumor, NBTXR3 could have a number of advantages: the physical and universal mode of action that could be used widely across oncology, the one-time local injection and good fit within existing medical practice already used as a basis for cancer treatment, as well as a promising chronic safety profile and well-established manufacturing process.

After 18 months of development, the Company presented preclinical proof of concept demonstrating that NBTXR3 actively stimulates the host immune system to attack tumor cells.

Recently, Nanobiotix presented new translational data. Taken together, these non-clinical and preliminary clinical results confirm that NBTXR3 activated by radiotherapy could efficiently prime an adaptive antitumor immune response, turning "cold" tumors in "hot" tumors. Additionally, these results suggest that the physically-induced response and subsequent immune activation triggered by the NBTXR3 treatment could be generic. Results suggest that NBTXR3 activated by radiotherapy could transform tumors into an effective in situ vaccine, opening up very promising perspectives in the treatment of local cancer and metastases.

On top of the Company's core development activities, these findings could open new collaborations for NBTXR3 through combinations with other immuno-oncology drugs.

About NBTXR3

NBTXR3 is an injectable aqueous suspension of hafnium oxide nanoparticles designed as an innovative therapeutic agent for the treatment of solid tumors, currently in clinical development by Nanobiotix.

Once injected intratumorally, NBTXR3 can deposit high energy within tumors only when activated by an ionizing radiation source, notably radiotherapy. Upon activation, the high energy radiation is physically designed to kill the tumor cells by triggering DNA damage and cell destruction and improve clinical outcomes.

Promising results indicate that NBTXR3 activity could be applicable across solid tumors triggering immunogenic cell death, leading to an immune response, reinforcing a local and potentially systemic effect, and contributing to transform "cold" tumors into "hot" tumors. NBTXR3's major characteristics are represented by a high degree of biocompatibility, one single administration before and

during the whole therapy and the ability to fit into current standards of radiotherapy care.

NBTXR3 entered clinical development in 2011 in a Phase I/II with patients suffering from advanced soft tissue sarcoma of the extremities and is currently in the final stages of its subsequent phase II/III. In parallel, it is currently being tested in numerous Phase I/II clinical trials with patients suffering from locally advanced squamous cell carcinoma of the oral cavity or oropharynx (head and neck), liver cancer (hepatocellular carcinoma and liver metastasis), locally advanced or unresectable rectal cancer in combination with chemotherapy, head and neck cancer in combination with concurrent chemotherapy, and prostate adenocarcinoma.

About NANOBIOTIX: www.nanobiotix.com

Nanobiotix (Euronext: NANO / ISIN: FR0011341205) is a late clinical-stage nanomedicine company pioneering novel approaches to the treatment of cancer. The Company's first-in-class, proprietary technology, NanoXray, enhances radiotherapy energy with a view to providing a new, more efficient treatment for cancer patients.

NanoXray products are compatible with current radiotherapy treatments and are meant to treat potentially a wide variety of solid tumors including soft tissue sarcoma, head and neck cancers, liver cancers, prostate cancer, breast cancer, glioblastoma, etc., via multiple routes of administration.

NBTXR3 is being evaluated in: Soft tissue sarcoma (STS), head and neck cancers, prostate cancer, and liver cancers (primary and metastases). Additionally, head and neck cancer and rectal cancer trials led by Nanobiotix's Taiwanese partner, PharmaEngine, are underway in the Asia Pacific region.

The Company is also running research programs in immuno-oncology, with its lead product NBTXR3, which could have the potential to bring a new dimension to cancer immunotherapies.

Nanobiotix is listed on the regulated market of Euronext in Paris (ISIN: FR0011341205, Euronext ticker: NANO, Bloomberg: NANO: FP). The Company's Headquarters are based in Paris, France, with a U.S. affiliate in Cambridge, MA.

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Disclaimer

This press release contains certain forward-looking statements concerning Nanobiotix and its business. Such forward-looking statements are based on assumptions that Nanobiotix considers to be reasonable. However, there can be no assurance that the estimates contained in such forward-looking statements will be verified, which estimates are subject to numerous risks including the risks set forth in the reference document of Nanobiotix filed with the French Financial Markets Authority (Autorité des Marchés Financiers) under number D.17-0470 on April 28, 2017 (a copy of which is available on www.nanobiotix.com) and to the development of economic conditions, financial markets and the markets in which Nanobiotix operates. The forward-looking statements contained in this press release are also subject to risks not yet known to Nanobiotix or not currently considered material by Nanobiotix. The occurrence of all or part of such risks could cause actual results, financial conditions, performance or achievements of Nanobiotix to be materially different from such forward-looking statements.

This press release and the information that it contains do not constitute an offer to sell or subscribe for, or a solicitation of an offer to purchase or subscribe for, Nanobiotix shares in any country. At the moment NBTXR3 does not bear a CE mark and is not permitted to be placed on the market or put into service until NBTXR3 has obtained a CE mark.

About PEP503 (NBTXR3)

NBTXR3, the lead project of the NanoXray pipeline of Nanobiotix, is a nanoparticle formulation of hafnium oxide crystals for the local treatment of tumors to enhance the efficacy of radiotherapy. In August 2012, PharmaEngine licensed the development and commercialization rights of NBTXR3 in the Asia-Pacific region from Nanobiotix. In 2014, Nanobiotix presented the pilot study results for NBTXR3 in patients with soft tissue sarcomas at ASCO, which showed a good safety profile and positive signs of efficacy. Then the preliminary pilot study results in head and neck cancer patients (without receiving chemotherapy) presented at ASCO 2017 also showed promising signs of anti-tumor effect.

There are other indications being developed for NBTXR3 by Nanobiotix and PharmaEngine. These include head and neck cancer in patients receiving chemotherapy (Phase I/II, PharmaEngine), rectal cancer (Phase I/II, PharmaEngine), liver cancer (Phase I/II, Nanobiotix) and prostate cancer (Phase I/II, Nanobiotix). NBTXR3 has been classified as a class III medical device in many European and certain Asian countries.

About PharmaEngine (TWO: 4162)

PharmaEngine, Inc. is a biopharmaceutical company headquartered in Taipei, Taiwan with a wholly owned subsidiary, PharmaEngine Europe Sarl in Paris, France. PharmaEngine focuses on the development of new medications for the treatment of cancer and Asian prevalent diseases. PharmaEngine has three ongoing projects: ONIVYDE® has received regulatory approvals in 36 countries; PEP503 (NBTXR3) is in a global pivotal trial of soft tissue sarcoma and patient recruitment has been completed; and PEP06 is in preclinical development. For further information, please visit PharmaEngine's website at http://www.pharmaengine.com.

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